UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF INDIANA

ROBERT BRADBURN, Plaintiff, vs. C.R. BARD, INC., a corporation; BARD ACCESS SYSTEMS, INC., a corporation; and DOES 1 through 10 inclusive, Defendants.	Case No.: 3:19-cv-925 **COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE.** **(2) FAILURE TO WARN** **(3) MANUFACTURING DEFECT** **(4) DESIGN DEFECT** **(5) BREACH OF IMPLIED WARRANTY** **(6) BREACH OF EXPRESS WARRANTY** **(7) FRAUDULENT CONCEALMENT** **DEMAND FOR JURY TRIAL**

COMES NOW the Plaintiff, ROBERT BRADBURN, (who hereinafter shall be referred to as the "Plaintiff" or as "WRIGHT"), by and through his undersigned counsel, and brings this Complaint against C.R. Bard, Inc.; Bard Access Systems, Inc.; and DOES 1 through 10 (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages relating to Defendant's design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade name of Bard PowerPort® M.R.I. Implantable Port (hereinafter "PowerPort", or "Defective Device").

PARTIES

2. Plaintiff, Robert Bradburn, is an adult resident of St. Joseph County, Indiana and claims damages as set forth below.

3. Defendant C.R. Bard, In. ("Bard") is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into

interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort.

4. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. BAS conducts business throughout the United States, including the State of Indiana, and is a wholly owned subsidiary of C.R. Bard. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort.

5. Plaintiff is ignorant of the true names and capacities of defendants sued herein as DOES 1 through 10, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will amend this complaint to allege their true names and capacities when ascertained.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

7. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are produced, sold to and consumed by individuals in the State of Indiana, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

8. Defendants have and continue to conduct substantial business in the State of Indiana and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

9. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Indiana, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

10. The Bard PowerPort® M.R.I. Implantable Port ("PowerPort") is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

11. According to the BAS, the PowerPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

12. The intended purpose of the PowerPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

13. The PowerPort is a system consisting of two primary components: an injection port and a polyurethane catheter.

14. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

15. The PowerPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."

16. According to BAS marketing materials, the polyurethane catheter "has less propensity for surface biodegradation, making it more resistant to environmental stress cracking."

17. The PowerPort is commonly used in patients with cancer to facilitate the administration of chemotherapy or other long-term infused medications.

18. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

19. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of

the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacture can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

20. In *Medtronic, Inc.* v. Lohr, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

21. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

22. At all times relevant, Defendants misrepresented the safety of the PowerPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the PowerPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids,

parenteral nutrition solutions, and blood products.

23. At all times relevant to this action, Defendants knew and had reason to know, that the PowerPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

24. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with PowerPorts had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

25. Soon after the PowerPort was introduced to market, which was years before Plaintiff was implanted with his device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the PowerPort was migrating post-implantation. Defendants also received large numbers of AERs reporting that PowerPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage;

b. cardiac/pericardial tamponade;

c. cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. severe and persistent pain;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

26. Defendants were aware or should have been aware that the PowerPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

27. Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring.

28. Rather than alter the design of the PowerPort to make it safer or adequately warn physicians

of the dangers associated with the PowerPort, Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of numerous reports of catheter migration and associated injuries.

29. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:

a. Adequately Inform or warn Plaintiff, his prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the PowerPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO ROBERT BRADBURN

30. On or about February 20, 2019, Plaintiff underwent placement of the PowerPort model number 1808000, lot number RECK0973. The device was implanted by Dr. Stephen Kim for the purpose of ongoing chemotherapy.

31. Defendant, BAS directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the PowerPort that was implanted in Plaintiff.

32. Plaintiff underwent necessary chemotherapy to treat his B-Cell Lymphoma.

33. On or about September 12, 2019 at Elkhart General Hospital, the PowerPort catheter was found to have migrated, retracted and looped on itself near the jugular access site with the distal tip positioned within the subclavian vein. Plaintiff underwent surgery at Elkhart General Hospital to remove the defective device and to correct complications it had caused him.

34. Due to the defective device, Plaintiff suffered damages and continues to suffer damages including, but not limited to, undergoing an unnecessary major surgery, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, cardiac tamponade.

35. The Defendants concealed—and continue to conceal—their knowledge of the PowerPort's

unreasonably dangerous risks from Plaintiff and his physicians.

36. Numerous reports of PowerPort catheter migration or dislodgment in the absence of physician error were recorded and reported BAS prior to prior to the implantation of the PowerPort in Plaintiff.

37. However, BAS continued to actively and aggressively market the PowerPort as safe, despite knowledge of numerous reports of catheter migration or dislodgment. BAS, with Bard's knowledge and consent, utilized marketing communications, including the Instruction for Use, and direct communications from sales representatives to Plaintiff's health care providers to intentionally misled his health care providers into believing these failures were caused by physician error.

38. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of catheter migration or dislodgment associated with the PowerPort.

39. Rather than alter the design of their product to make it safer or warn physicians of the dangers associated with the PowerPort, the Defendants chose to continue their efforts to promote their defective product.

40. Plaintiff's physicians relied upon the representations, including the instructions for use distributed with the product implanted in Plaintiff, and advertisements to Plaintiff's detriment.

41. The Defendants knowingly concealed the dangerous propensity of this device to migrate and/or dislodge, necessitating surgical intervention. Defendants' further concealed their knowledge that these failures were occurring, and that the failures were known to be causing serious injuries.

42. As a result of the failure of the Defendants' PowerPort and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

43. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the PowerPort.

44. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the PowerPort, which has caused and will continue to cause Plaintiff's various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendants Bard, BAS, and DOES 1 through 10, inclusive)

45. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

46. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the PowerPort.

47. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the PowerPort before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the PowerPort;

c. Failing to conduct sufficient post-market testing and surveillance of the PowerPort;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the PowerPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the PowerPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the PowerPort; and

f. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its adverse effects.

48. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

49. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted

grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants Bard, BAS, and DOES 1-10)

50. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

51. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

52. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

53. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the PowerPort that was implanted into Plaintiff that the PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

54. Defendants further knew that these devices were dislodging and migrating for reasons other than the physician's initial placement of the device or post-implant maintenance.

55. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort; no reasonable health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

56. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

57. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

58. The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

59. When Plaintiff was implanted with the device, Defendants Bard and BAS failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

60. Defendants intentionally underreported the number and nature of adverse events associated with dislodgement and migration of the devices to Plaintiff's health care providers, as well as the FDA.

61. Neither Plaintiff nor his health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

62. Plaintiff and his health care providers used PowerPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to malfunction.

63. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

64. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at

trial. In other words, had Defendants provided adequate warnings, Plaintiff and his physicians would not have used the device.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against Defendants Bard, BAS, and DOES 1-10)

65. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

66. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort that was implanted into Plaintiff.

67. The PowerPort implanted in Plaintiff contained a manufacturing defect when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical unites of the same product line.

68. Upon information and belief, the PowerPort implanted in Plaintiff varied from its intended specifications.

69. Plaintiff and his health care providers used the PowerPort in a way that was reasonably foreseeable to Defendants.

70. The device's manufacturing defect was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants Bard, BAS, and DOES 1-10)

71. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

72. The PowerPort implanted in the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

73. The PowerPort was in a defective condition at the time that it left the possession or control of Defendants.

74. The PowerPort was unreasonably dangerous to the user or consumer.

75. The PowerPort was expected to and did reach the consumer without substantial change in its condition.

76. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

77. As a direct and proximate result of the PowerPort's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Defendants Bard, BAS, and DOES 1-10)

78. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

79. Defendants impliedly warranted that the PowerPort was merchantable and fit for the ordinary purposes for which it was intended.

80. When the PowerPort was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

81. The Plaintiff, individually and/or by and through his physician, relied upon Defendants' implied warranties of merchantability in consenting to have the PowerPort implanted in him.

82. Defendants breached these implied warranties of merchantability because the PowerPort implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

83. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective PowerPort in the Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

84. The PowerPort was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

85. As a direct and proximate result of Defendants' breaches of the aforementioned implied

warranties, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Defendants Bard, BAS, and DOES 1-10)

86. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

87. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

88. The PowerPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

89. At all relevant times, the PowerPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

90. Plaintiff, his physicians, and the medical community reasonably relied upon the Defendants' express warranties for the PowerPort.

91. At all relevant times, the PowerPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

92. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

93. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against Defendants Bard, BAS, and DOES 1-10)

94. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein. as if fully set forth herein.

95. Defendants fraudulently concealed information with respect to the PowerPort in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the PowerPort was safe and fraudulently withheld and concealed information about the substantial risks of using the PowerPort;

b. Defendants represented that the PowerPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the PowerPort was not safer than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

d. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

96. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the PowerPort.

97. The concealment of information by the Defendants about the risks of the PowerPort was intentional, and the representations made by Defendants were known by Defendants to be false.

98. The concealment of information and the misrepresentations about the PowerPort was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

99. Plaintiff and his physicians relied upon the representations and were unaware of the substantial risks of the PowerPort which the Defendants concealed from the public, including Plaintiff and his physicians.

100. As a direct and proximate result of the Defendants' actions, omissions and

misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

101. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

102. Had Defendants not concealed this information, neither Plaintiff's nor his health care providers would have consented to using the device in Plaintiff.

PUNITIVE DAMAGES

103. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and his health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the PowerPort. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and his health care providers, regarding the cause of dislodgement and migration failures of the device.

104. Defendants had knowledge of, and were in possession of evidence demonstrating that, the

PowerPort caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the PowerPort, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the PowerPort and consumers from agreeing to being implanted with the PowerPort, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the PowerPort.

105. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described in this complaint.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgement be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded his full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff.

h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: October 18, 2019

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